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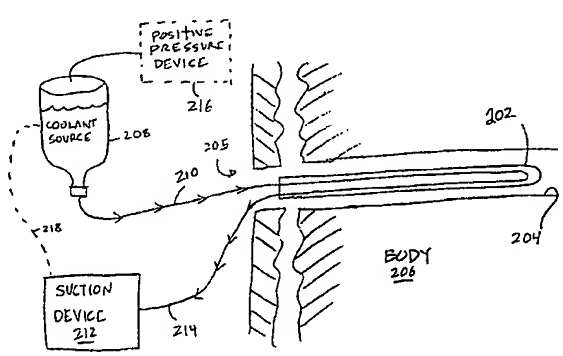

(57) **Abstract:** Cooling catheters are used with various new operating techniques. A catheter includes a continuous, internal path extending from a supply opening (at the proximal end) to the catheter's distal end, and then back to a return opening (at the proximal end). This path is sealed, preventing any contact between the coolant and the patient. This catheter may be constructed with various structural features, such as a multi-lumen coolant path, a heat exchange bundle of multiple thin hollow fibers, various shapes, etc. With one exemplary operating technique, physicians insert the catheter's distal end into a patient's body. After attaching the supply opening to a coolant source, suction is applied to the return opening, causing coolant to enter the catheter from the coolant source, and thereafter travel within the predefined coolant path. The use of suction has numerous advantages, including the tolerance of thinner catheter walls, which are more conductive to heat transfer. Additionally, if any leaks occur in the catheter, the surrounding bodily fluids are sucked into the catheter rather than leaking coolant into the patient's body. In another embodiment, which may operate under positive pressure and/or suction, the coolant comprises a slushy medium of ice particles in a liquid coolant. When the ice crystals melt, they remove substantial heat from the surrounding tissue or bodily fluid without appreciably changing the coolant's temperature.

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OPERATIONAL ENHANCEMENTS FOR USING COOLING CATHETERS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention concerns various operating techniques to improve the use of cooling catheters.

2. Description of the Related Art

In warm blooded creatures, temperature regulation is one of the most important functions of the body. Despite the known importance of properly maintaining body temperature, scientists have discovered certain beneficial effects of artificially inducing a hypothermic state. For instance, cooling the body can help regulate vital functions during surgery by lowering the metabolism. With stroke, trauma, and other pathological conditions, it is believed that hypothermia can also reduce the permeability of the blood/brain barrier, inhibit the release of damaging neurotransmitters, inhibit calcium mediated effects, inhibit brain edema, and lower intra cranial pressure. Regardless of the particular mechanism, the present invention understands that fevers degrade the outcomes for patients suffering from brain trauma or stroke, and moreover that hypothermia might improve the outcomes for such patients.

Hypothermia may be induced locally or systemically. With local hypothermia, physicians focus their cooling efforts on a particular organ, limb, anatomical system, or other region of the body. With systemic hypothermia, doctors universally lower body temperature without particular attention to any body part.

Under one technique for inducing systemic hypothermia, physicians cool the patient's entire body by packing it in ice. Although this technique has been used with some success, some physicians may find it cumbersome, and particularly time consuming. Also, it is difficult to precisely control body temperature with ice packing. As a result, the patient's body temperature overshoots and undershoots the optimal temperature, requiring physicians to add or remove ice. Furthermore, there is some danger of injuring the skin, which is necessarily cooled more than any other body part.

In another approach to systemic hypothermia, the patient is covered with a cooling blanket, such as an inflatable air- or water-filled cushion. Physicians control the patient's temperature by regulating the temperature of the inflation medium. Some delay is inherent in this system, first for a cooling element to change the temperature of the cooling medium, and then for the temperature adjusted cooling medium to cool the desired body part. This delay is even longer if the targeted body part is an internal organ, since the most effective cooling is only applied to the skin, and takes some time to successively cool deeper and deeper layers within the body.

The present invention recognizes that a better approach to inducing hypothermia is by circulating a cooling fluid through a cooling catheter placed inside a patient's body. The catheter may be inserted into veins, arteries, cavities, or other internal regions of the body. The present assignee has pioneered a number of different cooling catheters and techniques in this area. Several different examples are shown U.S. Application No. 09/133,813, entitled "Indwelling Heat Exchange

Catheter and Method of Using Same," filed on August 13, 1998. Further examples are illustrated in U.S. Application No. 09/294,080, entitled "Catheter With Multiple Heating/Cooling Fibers Employing Fiber Spreading Features," filed on April 19, 1999. The foregoing applications are hereby incorporated into the present application by reference. Among other disclosure, these applications depict catheters where the tip region includes multiple hollow fibers. The fibers carry a coolant that is circulated through the catheter. The thin walls and substantial surface area of the fibers are conductive to the efficient transfer of heat from surrounding body fluids/tissue to the coolant, thereby cooling the patient.

Advantageously, cooling catheters are convenient to use, and enable doctors to accurately control the temperature of a targeted region. In this respect, cooling catheters constitute a significant advance. Nonetheless, the performance, efficiency, safety, and reliability of these catheters can be improved.

SUMMARY OF THE INVENTION

Broadly, the present invention concerns new operating techniques to improve the use of cooling catheters. These techniques are employed with a catheter that includes opposing distal and proximal ends. Inside the catheter, a continuous coolant path extends from a supply opening (at the proximal end) to the distal end, and then back to a return opening (also at the distal end). This path is sealed, preventing any contact between coolant flowing inside the path and the body tissue or fluid surrounding the catheter. This catheter may be constructed with various

structural features, such as a multi-lumen coolant path, a heat exchange bundle of multiple thin hollow fibers, various shapes, etc.

With one exemplary operating technique, physicians insert the catheter's distal end into the patient's body. After attaching the supply opening to a coolant source, suction is applied to the return opening, causing coolant to enter the catheter from the coolant source, and thereafter travel through the catheter along the predefined coolant path.

In another embodiment, which may operate under suction and/or positive pressure, the coolant comprises a slushy mix of liquid along with ice particles. When the ice particles melt, they remove substantial heat from the surrounding tissue or bodily fluid without appreciably changing the coolant's temperature. By maintaining its cool temperature, the coolant retains its heat absorbing effectiveness for a longer time.

Another technique of this invention improves heat exchange as follows. Two openings are made in the treatment region, and the catheter is inserted with sufficient depth such that it progresses through the first opening, into the body cavity, and partially out the second opening. As one example, the openings may be cut to provide access to the vena cava. With this insertion scheme, the catheter is fully exposed to the treatment region. Moreover, the catheter need not provide "round-trip" coolant circulation. Namely, the catheter may convey the coolant in a single direction, with the fluid being removed from the catheter's distal tip, which protrudes from the second opening. This technique optimizes cooling efficiency by promptly

removing coolant that has already warmed during a one-way traversal of the catheter.

Also disclosed are other techniques that use external cooling devices concurrently with catheters. Some examples include forced air cooling blankets; cooling helmets filled with gel or cold pack material; blowing air over the body to cool by convection; applying a cold collar to cool the carotid artery; applying cold air or fluid to the airways in the head, such as sinuses or oropharynx; and using cold inserts with bodily orifices.

Accordingly, the invention may be implemented to provide various methods to improve the use of cooling catheters. In another embodiment, the invention may be implemented to provide an apparatus, such as a system for the practice of such methods.

The invention affords its users with a number of distinct advantages. First, coolant circulation by suction is beneficial because it may be applied to catheters with thinner walls. Namely, thinner walls are permissible since the resultant fluid pressure is limited to a "zero," i.e., vacuum pressure. This contrasts with positive pressure systems, where the upper pressure is potentially unlimited. Moreover, with thinner walls, the catheter exchanges heat more effectively. Additionally, if any leaks occur in the catheter, the surrounding bodily fluids are sucked into the catheter rather than leaking coolant into the patient's body. Other advantages are provided by the use of slushy coolant, including a mix of ice particles and liquid. Chiefly, when the ice particles melt, they remove heat from the surrounding tissue or bodily fluid

without appreciably changing the coolant's temperature. For example, the heat of fusion for water ice is about seventy-nine calories per gram. Thus, the coolant maintains its effectiveness in removing heat from the body. The invention also provides a number of other advantages and benefits, which should be apparent from the following description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic diagram of a generalized heat exchange catheter in accordance with the invention.

FIGURE 2 is a schematic diagram of a catheter cooling system in accordance with the invention.

FIGURE 3 is a flowchart depicting a sequence using suction to circulate coolant through a cooling catheter, in accordance with the invention.

FIGURE 4 is a flowchart depicting a sequence for preparing and circulating a slushy coolant through a cooling catheter, in accordance with the invention.

FIGURE 5 is a diagram showing a forced air blanket for enhanced cooling according to the invention.

FIGURE 6 is a diagram showing a cooling helmet for enhanced cooling according to the invention.

FIGURE 7 is a diagram showing a convection system for enhanced systemic cooling according to the invention.

FIGURE 8 is a diagram showing a cold collar for enhanced cooling according to the

invention.

DETAILED DESCRIPTION

The nature, objectives, and advantages of the invention will become more apparent to those skilled in the art after considering the following detailed description in connection with the accompanying drawings. As mentioned above, the invention concerns various operating techniques to improve the use of cooling catheters.

HARDWARE COMPONENTS & INTERCONNECTIONS

This invention concerns a catheter having an elongated body housing a sealed, internal coolant path. The catheter is designed to internally circulate a coolant, and thereby cool tissue or fluid surrounding the catheter without any contact between the coolant and the body.

This invention may be used with a variety of different catheter designs, one example of which appears in FIGURE 1. The catheter 100 includes a housing with a distal end 106 and a proximal end 108. The catheter 100 has largely coextensive coolant supply 112 and return 114 lines, whose distal ends being connected to an elongated heat transfer extension 102 of the catheter; although shown side-by-side in FIGURE 1, the lines 112, 114 may be arranged in a different way, such as concentrically. The heat transfer extension 102 includes an internal coolant flow path 104 that routes coolant from the supply line 112, to the catheter's distal tip, and then to the return line 114. Thus, the coolant travels longitudinally out and back

through the sealed path 104 inside the catheter without contacting the tissue or body fluid surrounding the catheter. Throughout its path, the coolant absorbs heat from the bodily tissue or fluid surrounding the catheter.

The supply and return lines 112, 114 include respective supply and return openings 116, 118 for coupling the catheter 100 to a pump or other mechanism (not shown) for circulating coolant through the catheter. This coupling may occur, for example, through intermediate conduits such as tubes, pipes, etc.

The teachings of the present invention may be applied to a number of different catheter designs. For example, the number of paths, supply lines, return lines, and other such features may be increased to increase flow, heat exchange, etc. Furthermore, this catheter may be constructed with various other structural features, such as a multi-lumen coolant path, a heat transfer extension made of multiple thin hollow fibers, a coiled heat transfer extension, and various other designs. The above-identified applications disclose several different catheter design embodiments in greater detail.

OPERATION

As mentioned above, this invention concerns various techniques to improve the use of cooling catheters. These techniques may be implemented using the representative catheter 100 described above, or with completely different designs. As explained in greater detail below, one process of this invention involves circulating coolant under suction rather than positive pressure. Another illustrated process

achieves more effective cooling by using a mix of liquid and ice particles as the coolant.

Using Suction to Circulate Coolant

FIGURE 3 shows a sequence 300 to illustrate one example of the method aspect of the present invention. For ease of explanation, but without any intended limitation, the example of FIGURE 3 is described in the context of FIGURE 2. The operations 300 begin in step 302, where physicians prepare the patient (not shown) for treatment. This may involve cleaning and disinfecting skin, removing hair, administering medicine, and other known procedures to ready the patient for surgery or other treatment. Also in step 302, physicians prepare an existing body opening or create a new opening 205 for insertion of the catheter 202. As an example of creating a new opening, doctors may cut an appropriately located incision or puncture in the groin, for insertion of the catheter into /the femoral artery or vein. The opening 205 leads to a body cavity 204, such as the vena cava, or different vein, artery or region.

In step 304, physicians insert the catheter 202 into the opening 205, and feed the catheter further inside the body to a desired position in the cavity 204. The catheter may be inserted through a device (not shown), such as an introducer sheath, nozzle, tube, funnel, or another device designed to position the catheter during insertion; this is especially beneficial for catheters with components that are pre-shaped or might tend to spread apart.

In step 306, physicians attach the supply line 210 of the catheter 202 to a coolant source 208. The coolant source 208 may include, for example, one or more syringes, pumps, gravity feed systems, or another appropriate device for circulating coolant through the catheter 202. One specific example is the Y-connector disclosed in the '813 application identified above.

Although presently described in the context of a cooling medium, the "coolant" may be a cooling fluid or a heating fluid, depending upon the particular application. In either case, heat exchange is occurring, and the heating/cooling fluid is nonetheless exemplified by "coolant." In many cases, the use of coolant may be especially useful to induce a controlled level of systemic hypothermia concurrent with surgery. The coolant comprises saline, carbon dioxide, or another hypoallergenic and inert substance that is safe for internal use in the body and will not cause any injury if it leaks from the catheter 202.

In step 308, physicians connect the return line 214 to a suction device 212 and apply suction to the catheter 202. The suction device 212 may comprise any suitable device for applying suction to the catheter, such as a positive displacement pump, syringe, syringe pump, peristaltic pump, diaphragm pump, etc. The suction device is selected to provide a desired level of suction appropriate to the cross-sectional area of the coolant path, viscosity of the coolant, volume of coolant in the path, and other properties. As an example, the suction device 212 may provide a level of suction that is less than the patient's blood pressure, and also less than the normal atmospheric pressure of 14.7 pounds per square inch absolute.

When suction is applied in step 308, this draws coolant from the source 208, through the catheter's coolant path , and ultimately to the suction device 212. Optionally, the suction device 212 may replenish the source 208 by returning coolant through a transfer line 218. As the coolant passes through the catheter 202, and especially the heat exchange extension, the coolant absorbs heat from the surrounding body tissue and/or fluid. In one embodiment, the surrounding body fluid is blood.

As an optional measure, positive pressure may be applied to the coolant, and thereby strengthen the coolant flow (step 310). This is performed using a positive pressure device 216, which may be attached to the coolant source 208 (as shown), the catheter's supply line, or another component of the system upstream of the catheter 202.

In step 311, physicians determine whether the targeted body region has reached the desired temperature. This may involve measuring the temperature of a concentrated target region (in the case of localized hypothermia), or the body core temperature (in the case of systemic hypothermia). If the target region has not reached the desired temperature, cooling is continued. When the desired temperature is reached, the physicians treat the patient (step 311). Treatment may involve surgery, or another medical procedure that benefits by induced hypothermia or hyperthermia.

After the treatment of step 311 is complete, physicians stop circulating the heat exchange fluid and remove the catheter in step 312. Alternatively, depending

upon the treatment being performed, physicians may decide to continue operating the catheter 202 for some time after treatment ends. For example, the patient can be re-warmed in a controlled manner after therapeutic hypothermia by using the body core temperature as a feedback signal to cause less-cool or possibly warm (> 38° Celsius) saline to flow through the catheter. In re-warming the patient, physicians monitor the warm-up rate to avoid re-warming too rapidly or too slowly. After removing the catheter, physicians close the patient's incision (if any) and perform any other applicable post treatment procedures. After step 312, the sequence ends in step 314.

The foregoing process has a number of advantages. First, this technique permits the use of a coolant path with thinner walls. This is possible since the fluid pressure is limited to "zero" (vacuum) pressure. And, with thinner walls, the catheter exchanges heat more effectively. Furthermore, with the availability of thinner walls in this design, the walls may be constructed of heat conductive materials such as Aluminum and Mylar, which are unsuitable for use in catheters with thicker walls. As another advantage, any leaks that occur in the catheter cause the surrounding bodily fluids to be sucked into the catheter rather than leaking coolant into the patient's body.

The following description introduces an additional enhancement to the sequence 300, realized by using suction to circulate coolant. Namely, during step 311 leaks in the catheter 202 may be detected by examining the return coolant for the presence of blood or other bodily fluids. As one example, the return coolant

(drawn by the suction device 212 from the catheter 202) may be examined manually by sight (unaided or with magnification). Alternatively, automated machinery may be used to examine return coolant; such machinery may include an optical detector such as a paired light source and light detector. Certain automated detectors operate on the principle that hemoglobin is a strong absorber of light, whereas water and saline coolant are transparent. Upon detecting bodily fluids in the return coolant, the automated detector may signal an alarm, alerting physicians to this condition.

Importantly, the steps 300 may be reordered in various ways without departing from the invention, as will be recognized by ordinarily skilled artisans (having the benefit of this disclosure). For instance, the catheter may be attached to the cooling hardware and then inserted into the body, or vice versa.

Slushy Heat Exchange Medium

FIGURE 4 shows a sequence 400 to illustrate another example of the method aspect of the present invention. For ease of explanation, but without any intended limitation, the example of FIGURE 4 is described in the context of the hardware of FIGURE 2. For brevity and ease of explanation, details are omitted from operations of FIGURE 4 that resemble operations of FIGURE 3, described previously.

The operations 400 begin in step 402, where physicians prepare the patient for treatment. This may entail similar operations as described above in FIGURE 3. In step 404, physicians prepare the coolant. One novel feature of the present invention is that the coolant comprises a "slushy" mix including a coolant liquid with

many ice particles, such as ice crystals. The liquid and solid ice particles may have the same chemical composition (i.e., both water), they may be different, or there may be a combination of similar and dissimilar materials. Some exemplary materials for use as coolant liquid and/or ice particles include saline solution, carbon dioxide, and other hypoallergenic and inert substances that are safe for internal use in the body and will not cause any injury upon leakage from the catheter 202. The coolant liquid and/or ice particles may also include additives to control the ice particle size, lower freezing point, etc. As an example, the ice particles may be smaller than 0.5 millimeters in every dimension. The volume, mass, or number of ice particles is carefully selected with respect to coolant volume to balance the desire for high cooling efficiency (provided by higher ice content) with the need for reasonable viscosity, clump-free liquid flow (provided by lower ice content).

As an important aspect of step 404, care is taken to avoid introducing air into the slushy mix; alternatively, air is removed from the slushy mix with an appropriate mechanism, such as a hydrophilic membrane. One technique to help avoid air entrainment is to start step 404 with water that has been degassed, i.e., purged of entrained nitrogen and other gases.

In step 406, physicians insert the catheter 202 into the body opening 205, and feed the catheter further inside the body to a desired position in the cavity 204. In step 408, physicians attach the catheter 202 to coolant circulating hardware. The coolant circulating hardware may comprise any suitable device(s) for routing the coolant through the catheter 202. As an example, step 408 may be performed by

attaching the supply line of the catheter 202 to the coolant source 208, and connecting the return line 214 to the suction device 212 (as discussed above in FIGURE 3). The positive pressure device 216 may be used in substitution for, or in addition to, the suction device 212.

In step 410, the slushy mix is routed through the catheter 202. As the slushy mix passes through the catheter 202, and especially the heat exchange extension, the slushy mix absorbs heat from the surrounding body fluid. Namely, the ice portion of the mix absorbs heat from the surrounding bodily fluid and tissue, causing the ice to partially or completely melt. In the case of water, about seventy-nine calories of energy are required for one gram of ice to undergo a phase change from solid to liquid state without any related temperature change. Thus, despite the previous absorption of heat causing the ice to melt, the resultant coolant liquid retains the same temperature as the ice-water mix. Consequently, the slushy mix is effective in removing heat from the body, without fully expending its cooling potential.

During step 410, physicians also determine whether the targeted body region has reached the desired temperature. If the target region has not reached the desired temperature, cooling is continued. In one embodiment, cooling is continued by circulating the expended slushy mix, which is still cooler than the target bodily region despite the presence of melted and/or melting ice particles. As an alternative, the coolant source may continually or occasionally introduce new, unmelted slushy mix. When the desired temperature is reached, the physicians treat the patient (step 411).

After the treatment of step 411 is complete, physicians stop circulating the heat exchange fluid and remove the catheter in step 412. Or, depending upon the treatment being performed, physicians may decide to continue operating the catheter 202 for some time after treatment ends, perform controlled re-warming, etc. Also as part of step 412, the patient's incision (if any) is closed and any other applicable post treatment procedures are performed. The sequence ends in step 416.

Importantly, the steps 400 may be reordered in various ways without departing from the invention, as will be recognized by ordinarily skilled artisans (having the benefit of this disclosure).

Improved Cooling By Enhancing Circulatory Functions

This invention also includes various other techniques, such as improving cooling by enhancing operation of the circulatory system. This may be performed, for example, by slowing the patient's blood flow rate to increase the time of contact between the blood and the catheter. In another exaple, the patient's body cavity (e.g., vena cava) may be temporarily expanded to increase its cross-sectional size, and thereby permit a larger catheter and consequently greater heat exchange. Along these lines, cooling may also be improved by using suitable medication to prevent or limit the constriction of veins.

Dual Opening Catheter Insertion

Another technique of this invention improves heat exchange as follows. Two incisions are made in the treatment region, or one existing opening is used and one new incision made. The catheter is inserted with sufficient depth such that it progresses through the first opening, into the body cavity, and partially out the second opening. The openings may be defined to provide access to the vena cava for example. With this insertion scheme, the catheter is fully exposed to the treatment region. Moreover, the catheter need not provide "round-trip" coolant circulation. Namely, the catheter may convey the coolant in a single direction, with the warmed coolant being removed from the catheter's distal tip, which protrudes from the second opening. This technique optimizes cooling efficiency by promptly removing coolant that has already warmed during a one-way traversal of the catheter.

Using External Cooling Devices

Also disclosed are other techniques that use external coding devices concurrently with catheters. One example is a forced air cooling blanket, where air is blown over a liquid-filled blanket covering the patient (FIGURE 5). Another example of an external cooling device is a helmet filled with cool gel or a cold pack material to cool the brain (FIGURE 6). As still another example, the body may be systemically cooled by convection, using a stream of air (FIGURE 7). Another example involves the application of a cold collar to cool the carotid artery (FIGURE 8), applying cold air

or fluid to the sinuses, oropharynx, or other airways or cavities in the head (not shown), or applying cooled inserts (not shown) to bodily orifices.

Accordingly, the invention may be implemented to provide various methods to improve the use of cooling catheters. In another embodiment, the invention may be implemented to provide an apparatus, such as a system for use of such methods.

OTHER EMBODIMENTS

While the foregoing disclosure shows a number of illustrative embodiments of the invention, it will be apparent to those skilled in the art that various changes and modifications can be made herein without departing from the scope of the invention as defined by the appended claims. Furthermore, although elements of the invention may be described or claimed in the singular, the plural is contemplated unless limitation to the singular is explicitly stated.

Moreover, the present invention is presently described in the context of the human body merely for ease of illustration, without any intended limitation. The invention may also be practiced with other beings, such as mammals, birds, reptiles, or other creatures. Furthermore, although the foregoing discussion has described catheter use to induce a hypothermic state, ordinarily skilled artisans (having the benefit of this disclosure) will recognize that the invention also contemplates the use of catheters to induce systemic or local hyperthermia.

Additionally, although certain fluid flow paths have been specifically illustrated for ease of understanding, opposite direction flow paths may be used instead. In

such alternatives, references to "supply" or "return" conduits or ends are accordingly reversed.

CLAIMS

WHAT IS CLAIMED IS:

1. A method for operating a heat exchange catheter having a distal end and an opposing proximal end, the catheter including one or more flow paths extending from a supply opening at the proximal end to the distal end and back again to a return opening at the proximal end, the method comprising the operations of:

inserting the catheter's distal end into a patient's body;

attaching the supply opening to a source of heat exchange medium; and

circulating the heat exchange medium through the path by applying suction to the return opening.

2. The method of claim 1, the heat exchange medium comprising a liquid coolant whose temperature, prior to circulation through the path, is less than a temperature of the patient.

3. The method of claim 1, further comprising:

concurrent with operation of applying suction to the return opening, directing the heat exchange medium into the supply opening under positive pressure.

4. The method of claim 1, the inserting operation including insertion of the entire catheter into the patient's body, where the supply and return openings are coupled to conduits extending from the catheter outward of the patient's body.

5. The method of claim 1, the heat exchange medium including multiple ice particles suspended in a liquid coolant.

6. The method of claim 1, further comprising detecting leaks in the flow path by examining return coolant for presence of bodily fluids.

7. A method for operating a heat exchange catheter having a distal end and an opposing proximal end, the catheter including one or more flow paths extending from a supply opening at the proximal end to the distal end and back again to a return opening at the distal end, the method comprising the operations of:

inserting the catheter's distal end into a patient's body; and

circulating a slushy coolant mix through the path, the coolant mix including multiple ice particles and a liquid coolant.

8. The method of claim 7, the ice particles and liquid coolant comprising different states of the same material.

9. The method of claim 7, the ice particles and liquid coolant both being made

of water.

10. The method of claim 7, the ice particles and liquid coolant being a saline solution.

11. The method of claim 7, further comprising:

the ice particles experiencing at least partial melting during the circulating operation.

12. The method of claim 7, the circulating operation comprising:

attaching the supply opening to a source of the coolant mix and circulating the coolant mix through the path by applying suction to the return opening.

13. A Cooling system, comprising:

a catheter comprising:

a housing having a distal end and an opposing proximal end;

within the housing, one or more flow paths extending from a supply opening at the proximal end to the distal end and back again to a return opening at the proximal end;

a source of heat exchange medium attached to the supply opening; and

a vacuum device attached to the return opening.

14. The catheter of claim 13, the vacuum device comprising a positive displacement pump.

15. The catheter of claim 13, the vacuum device comprising a syringe.

16. The catheter of claim 13, the vacuum device comprising a peristaltic pump.

17. The catheter of claim 13, the vacuum device comprising a diaphragm pump.

18. The catheter of claim 13, at least one of the flow paths including walls made of aluminum.

19. The catheter of claim 13, at least one of the flow paths including walls made of Mylar.

20. A cooling system, comprising:

a catheter, comprising:

a housing having a distal end and an proximal end;

within the housing, one or more flow paths extending from a supply opening at the proximal end to the distal end and back again to a return opening at the proximal end;

means for supplying a heat exchange medium to the supply opening; and

vacuum means for applying suction to the return opening.

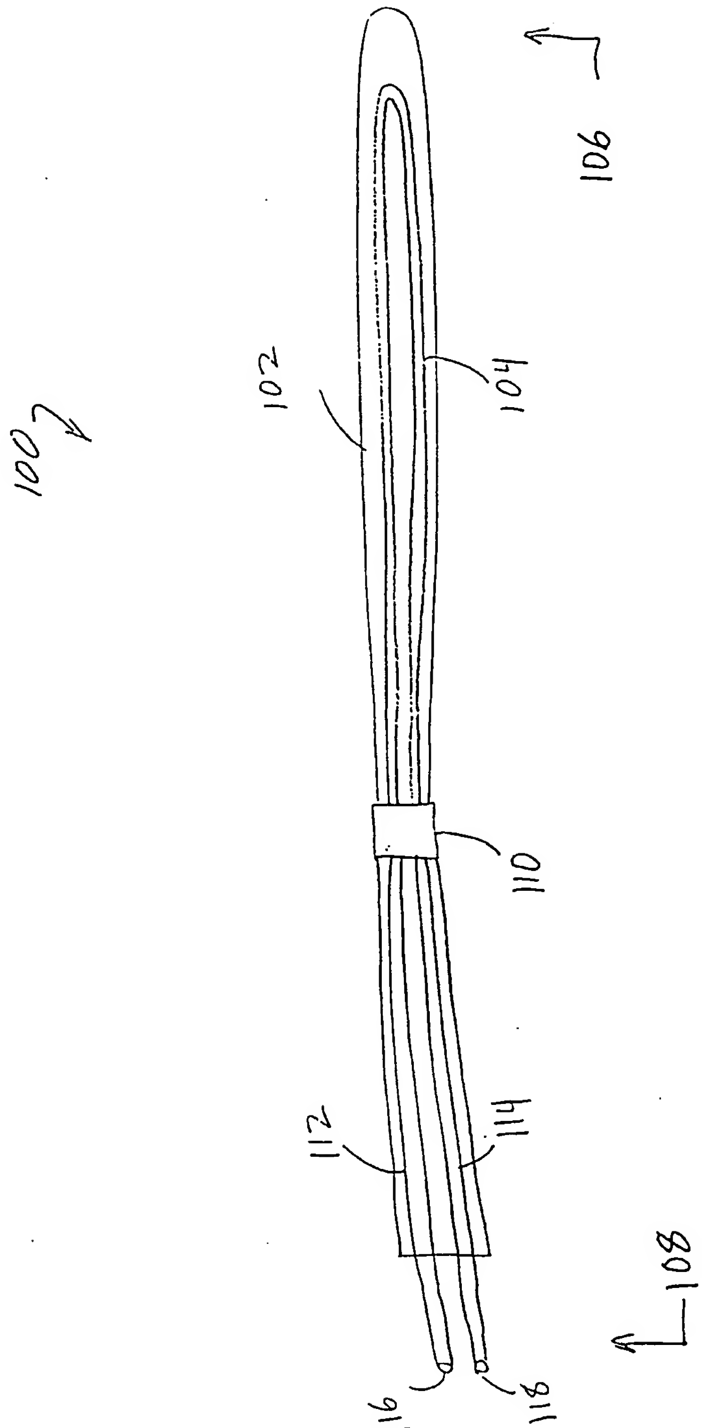


FIG. 1

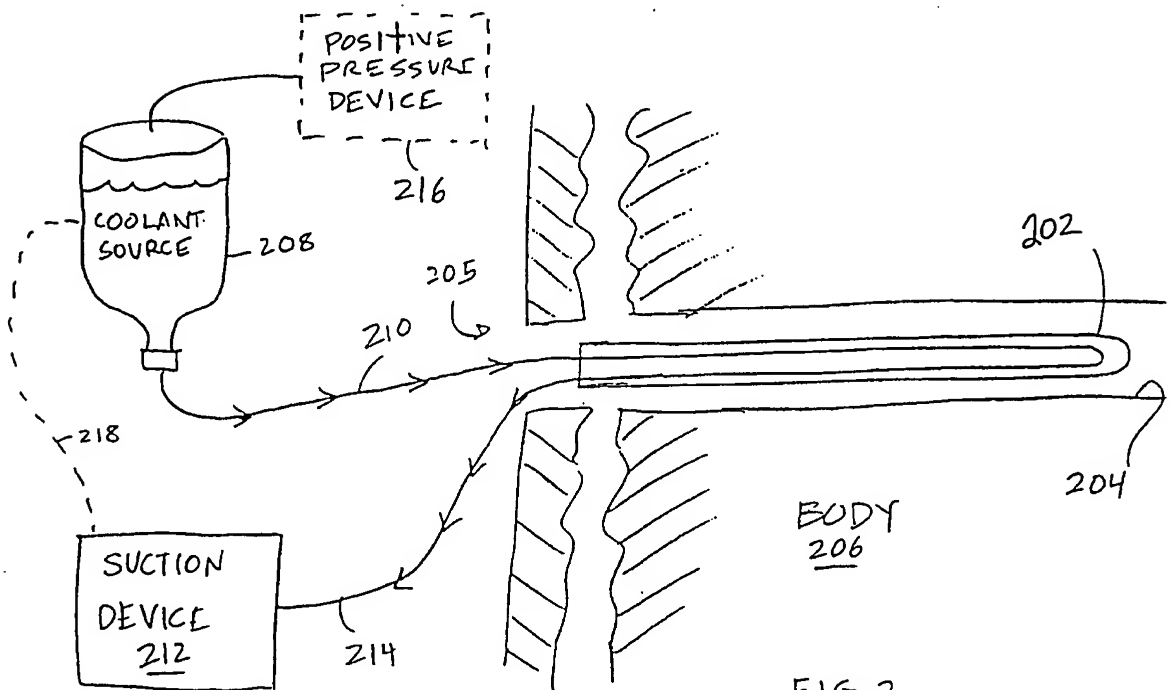

POSITIVE PRESSURE DEVICE
216
COOLANT SOURCE
208
205
210
202
218
204
BODY
206
SUCTION DEVICE
212
214

FIG. 2

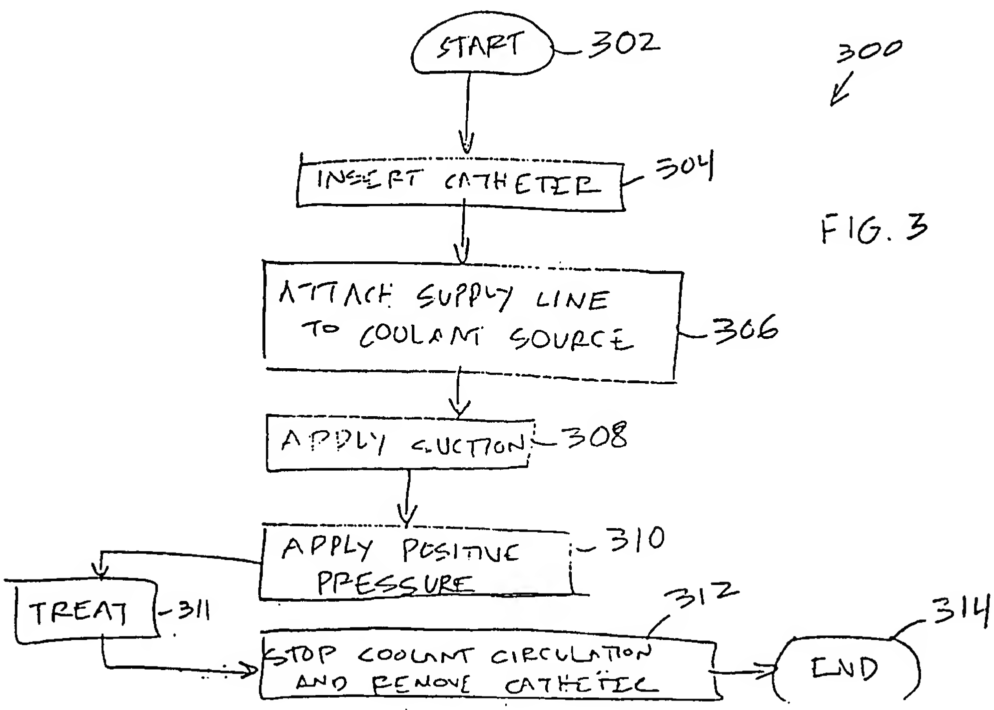
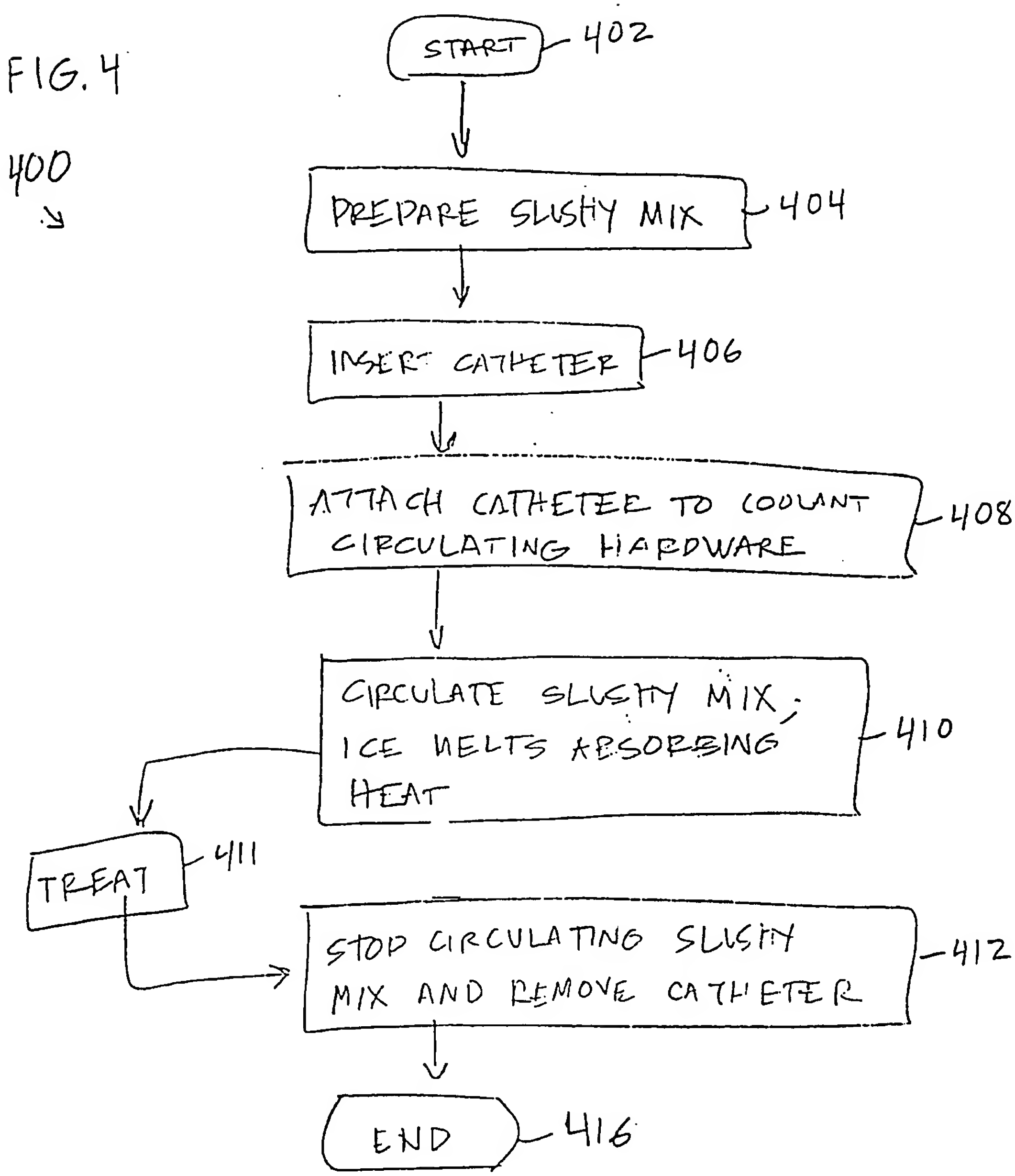

START
302
300
INSERT CATHETER
304
ATTACH SUPPLY LINE TO COOLANT SOURCE
306
APPLY SUCTION
308
APPLY POSITIVE PRESSURE
310
TREAT
311
STOP COOLANT CIRCULATION AND REMOVE CATHETER
312
END
314

FIG. 3

FIG. 4


400
START
402
PREPARE SLUSHY MIX
404
INSERT CATHETER
406
ATTACH CATHETER TO COOLANT CIRCULATING HARDWARE
408
CIRCULATE SLUSHY MIX; ICE MELTS ABSORBING HEAT
410
TREAT
411
STOP CIRCULATING SLUSHY MIX AND REMOVE CATHETER
412
END
416

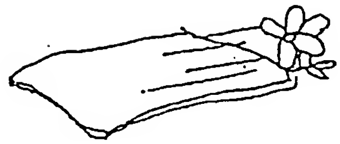


FIG. 5

FIG. 6

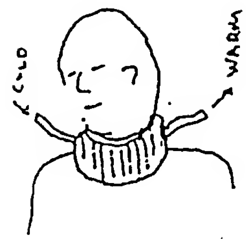


FIG. 8

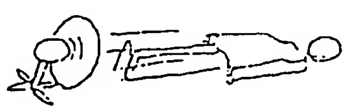


FIG. 7